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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,105	10/04/2001	Howard Milne Chandler	0141-2006	3619

7590 03/24/2006

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,105	CHANDLER ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-11,13-17,19-26,40 and 41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-11,13-17,19-26,40 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09 January 2006 has been entered.

Response to Amendment

2. Claims 40 and 41 have been added. Claims 1-4, 6-11, 13-17, 19-23, 25-26 and 40-41 are pending.

3. All rejections not reiterated herein below are withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 112

4. Claims 1-4, 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 9, "said detection step" lacks antecedent support.

Claim 20 is confusing because it appears that the amended materials have not been properly indicated. Claim 20 is further confusing because it is unclear how "symptoms" can be *diagnosed.* According to the dictionary, to "diagnose" is to recognize (as a disease) by sign and symptoms; to analyze the cause or nature of the problem; and to make a diagnosis. Therefore, a "symptom" such as bleeding can be either detected or observed but cannot be "diagnosed" using these definitions. This claim is more appropriately claimed as a method of detecting symptoms of a disease condition, as suppose to a method of diagnosing.

Claims 40 and 41 are vague and indefinite because the preamble of these claims do not correlate with the wherein clause.

Claim 41 is also confusing because a "sample" cannot have a "symptom".

Claim Rejections - 35 USC § 112

5. Claims 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendment of claim 20 does not have support in the specification as originally filed. Claim 20 is now directed to a method of diagnosing symptoms of a disease condition, which symptom is bleeding. The specification discloses detection of

intestinal bleeding as a symptom of a disease condition but does not disclose the diagnoses of a "symptom" per se. As stated above, it is unclear how "symptoms" can be *diagnosed.* According to the dictionary, to "diagnose" is to recognize (as a disease) by sign and symptoms; to analyze the cause or nature of the problem; and to make a diagnosis. Therefore, a "symptom" such as bleeding can be either detected or observed but cannot be "diagnosed" using these definitions.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-4, 6-11, 13-17, 19-23, 25-26, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barrows et al., (American Journal of Clinical Pathology. 1978. Vol. 69, No. 3, pp. 342-346) in view of Kuo (US 6,436,721) and Sy (WO 98/33069).

Barrows discloses an immunochemical test for human blood in feces using goat antibodies to hemoglobin. Barrows teaches that immunochemical identification of human blood in stool offers improved detection of lower gastrointestinal bleeding. Barrows teaches testing the samples using a radial immunoassay (RID) and the guaiac peroxidase method, and concludes that when both guaiac and RID tests were positive,

65% of the patients has documented sources of blood loss of the lower gastrointestinal tract. See page 343 and 344. Barrow teaches that patients with positive guaiac tests (heme) and no detectible blood by RID (globin) did not have evidence of lower gastrointestinal blood loss and about 25% has upper gastrointestinal bleeding. See page 345, table 3.

Barrows differs from the instant invention in failing to teach the use of a lateral flow chromatographic medium for the detection of occult blood.

Kuo, however, discloses the use of a flow matrix for detecting pairs of clinically related analyte. See column 2, line 24 through column 3, line 23. Kuo discloses that immunochromatographic test strips are ideal for providing a viable system for the determination of various analytes and provide quick and convenient means of determining those second analytes whose concentration or presence in the body fluid sample is clinically related to the concentration of the target analyte. See column 8, lines 8-12.

And Sy discloses a chromatographic medium for detecting analytes such as occult blood in a fecal sample. Pages 24-26.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by Barrows in order to simultaneously detect globin, using an immunochemical test, and heme, using a guaiac test, on the device of Kuo because Sy teaches that chromatographic medium are adaptable for detection of occult blood and analytes from a fecal samples. A skilled

artisan would have had a reasonable expectation of success in adapting the device of Kuo as taught by Sy to detect globin and heme because Barrows teaches that immunoassay to specifically detect hemoglobin provides a more sensitive and accurate test for upper and lower GI bleeding. Immunoassay assay also provide the additional advantage that it can be performed in laboratory facility with a minimum of equipment. A combination test for heme and globin incorporates the best features of the various tests for subclinical lower gastrointestinal bleeding.

Response to Arguments

8. Applicant's arguments filed 09 January 2006 have been fully considered but they are not persuasive.

The argument with respect to the 112, first paragraph rejection of claims 1-4 and 20-23 for lack of enablement is moot because this rejection has been withdrawn in view of the amendment to the claims. However, these amendments necessitate the new grounds of the rejection as stated above.

In response to applicant's argument that Barrows' technique is not directed to the problems associated with the prozone phenomenon nor to an assay which is able to distinguish between upper and lower intestinal track bleeding but, rather, to the problems associated with contaminants which may be present in stool samples, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the

differences would otherwise be obvious. See *Ex parte Obiaya,* 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Barrows discloses an immunoassay to detect hemoglobin using antibodies thereto; Barrows also discloses a chromogen method, using guiac, and concludes that when both guaiac and RID tests were positive, 65% of the patients has documented sources of blood loss of the lower gastrointestinal tract. See page 343 and 344. Barrow teaches that patients with positive guaiac tests (heme) and no detectible blood by RID (globin) did not have evidence of lower gastrointestinal blood loss and about 25% has upper gastrointestinal bleeding. See page 345, table 3. Therefore, Barrows teaches the invention. The difference between Barrows the claims is the lack of a lateral flow format. Kuo and Sy teach this difference. Kuo discloses that lateral test strips are well known in the art and one can modify them to detect a plethora of analytes using many different samples. See Kuo, column 8, lines 8-12. Sy discloses that occult blood in a test sample can be detected using lateral test strips, therefore, a skilled artisan would have had a reasonable expectation of success in modifying the method taught by Barrows in order to simultaneously detect globin, using an immunochemical test, and heme, using a guaiac test, on the device of Kuo because Sy teaches that chromatographic medium are adaptable for detection of occult blood and analytes from a fecal samples. Adapting the device of Kuo as taught by Sy to detect globin and heme as taught by Barrows involves only routine experimentation and because Barrows teaches that immunoassay to specifically detect hemoglobin provides a more sensitive and accurate test for upper and lower GI bleeding, one skilled in the art would have

been motivated to do so. Immunoassay assay also provide the additional advantage that it can be performed in laboratory facility with a minimum of equipment. A combination test for heme and globin incorporates the best features of the various tests for subclinical lower gastrointestinal bleeding.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
3/18/06